DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 3, 2014

Changzhou Dean Medical Instrument Company, Limited
% Ms. Diana Hong
Mid-Link Consulting Company, Limited
P.O. Box 120-119
Shanghai, 200120, China

Re: K134011
Trade/Device Name: General Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: August 7, 2014
Received: August 11, 2014

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K134011

Device Name

General Spinal System

Indications for Use *(Describe)*

The General Spinal System is intended for posterior pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients. It provides stabilization and immobilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities: (1) trauma (i.e. fracture or dislocation), (2) curvatures (scoliosis, kyphosis, and/or lordosis), (3) spinal tumor, (4) failed previous fusion, (5) pseudarthrosis, (6) spinal stenosis. It is not intended for pedicle screw fixation above T8. This device may be used with autograft and/or allograft.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

This 510(k) Summary of 510(k) information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K134011

1. Date of Submission: 08/06/2014

2. Sponsor Identification

Changzhou Dean Medical Instrument Co., Ltd.
No. 10, Jinshajiang Road, Xinbei District, Changzhou, Jiangsu, 213125, China

Establishment Registration Number: Not yet registered

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3. Submission Correspondent

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4. Proposed Device Identification

Common Name: General Spinal System
Proposed Device Name: General Spinal System
Classification Name: Pedicle screw spinal system
Product Code: MNI, MNH
Regulation Number: 21 CFR part 888.3070
Review Panel: Orthopedic

Intended Use Statement:

The General Spinal System is intended for posterior pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients. It provides stabilization and immobilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities: (1) trauma (i.e. fracture or dislocation), (2) curvatures (scoliosis, kyphosis, and/or lordosis), (3) spinal tumor, (4) failed previous fusion, (5) pseudarthrosis, (6) spinal stenosis. It is not intended for pedicle screw fixation above T8. This device may be used with autograft and/or allograft.

5. Predicate Device Identification

510(k) Number: K082617
Product Name: Trauson General Spinal System (GSS)
Manufacturer: Trauson (Jiangsu) Medical Instrument Co., Ltd.

510(k) Number: K042790
Product Name: CD HORIZON ® Spinal System
Predicate Device Name: CD HORIZON LEGACY 5.5mm Spinal System
Manufacturer: Medtronic SofamorDanek, Inc.USA

6. Device Description

The General Spinal System consists of Fixed-Angle Screws, Fix-Angle Reduction Screws, Rods, Cross Link and set screws.

It is made of Titanium Alloy (Ti6Al4VELI), which meets ASTM F136-02a, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications, which are widely used for surgical implants with well known biocompatibility.

The proposed devices are provided non-sterile. It is required to be sterilized via autoclave method to reach a SAL of 10^{-6} by the hospital prior to surgery. The recommended sterilization method was validated

per ISO 17665-1: 2006 Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standard:

ASTM F1717-04, Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model, including the following items:

- Static compression bending test;
- Dynamic compression bending test;
- Static torsion test.

8. Substantially Equivalent (SE) Conclusion

The General Spinal System is Substantially Equivalent to the predicate device with respect to intended use, technological characteristics and principles of operation.